

Fleminger, Inc.

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June 13, 2005

Sheldon T. Bradshaw, Esq.
FDA Chief Counsel
c/o Mr. Vincent de Jesus
Food and Drug Administration (HFS-830)
5100 Paint Branch Parkway
College Park, MD 20740-3835 Via Federal Express # 848540861041

Re: Application: Docket No. 2004Q-0083-Daily consumption of 40 ounces of typical green tea containing 710µg/mL natural (-)-epigallocatechin gallate (EGCG) may reduce the risk of certain forms of cancer....

Dear Mr. Bradshaw:

This is a follow-up to my letter dated May 31, 2005 in which I asked you if I might travel to your office for a meeting on June 13, 2005, after I presented a seminar on "Green Tea: From Medicine to Beverage" at the Johns Hopkins University School of Medicine in Baltimore, to answer any scientific questions that you might have about my application under FDA Docket No. 2004Q-0083 referenced above. I have not received a response from your office to my request.

Since using green tea as a health beverage to fight cancer is a very timely topic to the American healthcare providers and consumers alike, my seminar delivered at Hopkins generated a great deal of interest among the participants. I am enclosing a copy of the final pre-seminar announcement and the article entitled "Re-introducing Tea to the West-This Time to Fight Cancer" which was distributed to the participants, for your reference. The latter article was largely based on the scientific data submitted to the FDA in support of my application for the green tea qualified health claim, and the readers are referred to the FDA Docket Management website to view the entire application under Docket No. 2004Q-0083 for additional information. Since this article is written in a more concise and conceptual format, it may be of some help to your staff in completing their review process by June 17, 2005, the latest FDA-committed date for its final decision on my application. As always, please contact me if you and your staff have any questions concerning this application.

Thank you for your attention and cooperation.

Sincerely,


Sin Hang Lee, M.D.

Encl. Pre-conference announcement and re-print of "Re-introducing Tea to the West - This Time to Fight Cancer"

cc. Congressman Christopher Shays (c/o Mr. Tom McCabe), Congressman Bob Simmons, Congressman John B. Larson, Congresswoman Rosa L. DeLauro, Congresswoman Nancy L. Johnson, Senator Chris Dodd and Senator Joe Lieberman.

2004Q-0083

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Green Tea: From Medicine to Beverage

An evidence-based scientific presentation by

Sin Hang Lee, M.D., F.R.C.P.(C)

Founder of the Global Green Tea Movement

www.teaforhealth.com

Date:	Friday June 10, 2005
Time:	12:45 p.m. to 1:45 p.m.
Location:	Thomas B. Turner Building in the Tilghman Room at Johns Hopkins University School of Medicine



Title: "Drinking Tea" by Tang Yin 唐寅 (1470-1523)
(Original in Palace Museum, Beijing)

The 5000 year-old Art and Science of Drinking Green Tea is hidden in a poem written on this famous painting, which is translated into *English verbatim* followed by further interpretation in ().

What to do on a long day?
Made tea for myself.
Picked leaves from beneath the southern window.
Let soothing fragrance fill my mind.

(Tea is for people of an affluent society)
(Tea should be prepared with great care)
(Use fresh tea leaves to brew tea)
(Tea is for health, gratification in mind)